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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,071	08/22/2003	Philip A. Swain	11662-003-999	9609

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EXAMINER	
STEELE, AMBER D	
ART UNIT	PAPER NUMBER
1639	
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04/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,071	SWAIN ET AL.	
	Examiner	Art Unit	
	AMBER D. STEELE	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *125,126,128,131-138 and 142* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *125,126,128,131-138 and 142* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-99, 105-108, and 110 were canceled, claims 101-103 and 109 were amended, and new claims 111-124 were added in the amendment to the claims received on June 1, 2006.

The amendment to the claims received on February 16, 2007 amended claims 100-101, 118; canceled claims 102, 114-116; and added new claims 125-140.

The amendment to the claims received on October 9, 2007 canceled claims 100-101, 103-104, 109, 111-113, 117-124, 127, and 130 and amended claims 125 and 129.

The amendment to the claims received on June 12, 2008 amended claim 125, canceled claims 129 and 139-140, and added new claims 141-142.

The amendment to the claims received on January 26, 2009 amended claims 125-126, 128, 131-138, and 142 and canceled claim 141.

Claims 125-126, 128, 131-138, and 142 are currently pending and under consideration.

Election/Restrictions

2. Applicants elected, with traverse, Group I (previous claims 100-104) in the reply filed on June 1, 2006. The traversal was on the ground(s) that a serious burden to search Groups I and III did not exist. The traversal was found persuasive. Therefore, the restriction between Groups I and III (i.e. previous claim 109) was withdrawn. However, applicants did not traverse the restriction between Group I and Groups II or IV. The restriction was made final in the Office action mailed on August 17, 2006.

Priority

3. The present application claims status as a CON of 10/115,580 filed April 1, 2002 which is a CON of 09/882,803 filed June 14, 2001 which is a CON of 09/257,821 filed February 25, 1999 which is a CON of 08/720,487 filed September 30, 1996 (now U.S. Patent 5,876,727) which is a CIP of 08/563,673 filed November 28, 1995 (now U.S. Patent 5,760,184) which is a CIP of 08/414,971 filed March 31, 1995.

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/414,971, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/414,971 does not disclose nicotine or nicotine derivatives (i.e. nicotine metabolites of present Figure 19, nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucuronide). In addition, application No. 08/414,971 does not disclose branches CJ 1.3 or CJ 11.

The disclosure of the prior-filed application, Application No. 08/563,673, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Application No. 08/563,673 (U.S. Patent 5,760,184 does not disclose nicotine derivatives (i.e. nicotine metabolites of present Figure 19, nicotine-1'-N-oxide, trans-3'-hydroxycotinine, or nicotine glucuronide). In addition, application No. 08/563,673 does not disclose branches CJ 1.3 or CJ 11.

Therefore, the priority date for the present claim limitations of nicotine derivatives, CJ 1.3, and CJ 11 is September 30, 1996 (i.e. filing date of U.S. application 08/720,487 which is now U.S. Patent 5,876,727). The priority date for the claim limitation of nicotine is November 28, 1995 (i.e. filing date of U.S. application 08/563,673 which is now U.S. Patent 5,760,184). Therefore, the priority for the presently claimed invention as a whole is September 30, 1996.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on January 26, 2009 is being considered by the examiner in part (see below).

6. The information disclosure statement filed January 26, 2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Invention as Claimed

7. A pharmaceutical composition comprising a hapten-carrier conjugate said pharmaceutical composition comprising at least one hapten which is nicotine or a nicotine derivative and at least one carrier which is a pseudomonas exotoxin and wherein the hapten and the carrier are linked by a branch selected from the group of chemical moieties CJ 0 - CJ 1.1 and CJ 2 - CJ 11 and variations thereof.

Withdrawn Rejections

8. The rejection of claims 125-126, 128, 131-138, and 141-142 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of the claim amendments received on January 26, 2009.

9. The rejection of claim 142 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the claim amendments received on January 26, 2009.

10. The rejection of claims 125-126, 128, 131-138, and 141-142 under 35 U.S.C. 103(a) as being unpatentable over Walling et al. U.S. Patent 5,164,504 issued November 17, 1992 and Vyas U.S. Patent 4,483,793 issued November 20, 1984 is withdrawn in view of the claims amendments (e.g. pseudomonas exotoxin) received on January 26, 2009.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 125-126, 128, 131-138, and 142 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants point to page 10, lines 26-35; page 11, lines 4-8; and page 24, lines 19-23 to support the claim amendments received on January 26, 2009. However, the previously mentioned sections of the specification do not provide support for the Markush group for Q (e.g. Q is H, OH, etc.; see independent claim 125). Therefore, the Markush group is considered new matter. In addition, the limitation of claim 142 requiring an additional pharmaceutically acceptable carrier is not supported by the originally filed specification and is considered new matter.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 125-126, 128, 131-138, and 142 are rejected under 35 U.S.C. 102(e) as being anticipated by Swain et al. U.S. Patent 6,054,127 (effective filing date of March 31, 1995).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

For present claims 125-126, 128, 131-138, and 142, Swain et al. teach hapten-carrier conjugates capable of eliciting anti-hapten antibodies in vivo wherein the hapten is nicotine, the carrier is pseudomonas exotoxin, linkers including CJ0-CJ11 are utilized, multivalent haptens are utilized, adjuvants including aluminum phosphate, etc. are utilized, and administration is via peritoneal, topical, etc. routes (please refer to the entire specification particularly the abstract; columns 7, 10-11, 14, 19-21).

Therefore, the presently claimed invention is anticipated by the teachings of Swain et al.

Claim Rejections – 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 125-126, 128, 131-138, and 142 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walling et al. U.S. Patent 5,164,504 issued November 17, 1992 and Green et al. U.S. Patent 5,601,831 issued February 11, 1997.

For present claims 125-126 and 137-138, Walling et al. teach nicotine, cotinine, and cotinine derivative (i.e. nicotine derivative/metabolite) hapten-carrier conjugates wherein the hapten is cotinine, trans-3'-cotinine, or cotinine-N-oxide, the carrier can be various proteins or peptides, and the carrier is covalently bound to the hapten via direct linkage (i.e. CJ 0), $(CH_2)_2CONH$ (i.e. CJ 6 where n = 2), or as represented in Formula I (please refer to column 2) wherein X is a straight or branched chain, saturated or unsaturated, divalent radical which has from 1-10 carbon atoms and 1-2 hetero atoms selected from the group consisting of S, O, and NZ wherein Z is a C_1-C_3 alkyl group and Q is a functional group selected from –COOH, $-NH_2$, $-C(O)NHNH_2$, -O(CO)Cl, -CHO, -NCS, or –NCO (please refer to the entire specification particularly the abstract; Formulas I, IV, V, VI, , VII, VIII, IX, X, XI, XII, XV, and XVI; columns 1-8; Examples 1-8; claims 1-6; and Table 1). In addition, Walling et al. teach utilizing S, O, and NH molecules in the branches joining the hapten and the carrier (please refer to columns 2-6). Furthermore, Walling et al. teach utilizing the hapten-carrier conjugates as immugens and eliciting immune responses in various animals (please refer to column 6).

Regarding the limitations of claim 126 (i.e. n is from 3 to 20), MPEP § 2144.09 states the following: "homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197

USPQ 601 (CCPA 1978). Thus, the $(CH_2)_2CONH$ branch taught by Walling et al. (i.e. CJ 6 where n = 2; please refer to Examples 6-7; Formulas XV and XVI; and columns 2-6) is considered an obvious variant of CJ 6 where n = 3-20 (i.e. present claim 126).

The intended use of present claims 137-138 (i.e. suitable for parenternal, oral, dermal, or topical administration) does not alter the structure of the presently claimed hapten-carrier conjugate (please refer to MPEP § 2106). The limitation of claim 125 (i.e. "capable of eliciting an antibody response against nicotine in a human") is a functional limitation. Therefore, if the structure is the same, it is assumed that the structures have the same function (see MPEP § 2173.05(g)). In addition, the Office does not have the facilities and resources to provide the factual evidence needed in order to determine if the nicotine derivative hapten-carrier conjugates taught by Walling et al. differ from a nicotine derivative hapten-carrier conjugate that is suitable for parenternal, oral, dermal, or topical administration as presently claimed (i.e. present claims 137-138) or is capable of eliciting an antibody response against nicotine in a human (see claim 125). In the absence of evidence to the contrary, the burden is upon the applicant to prove that the nicotine derivative hapten-carrier conjugates as claimed are different from the ones taught by the prior art and to establish the patentable differences. See *in re Best* 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

For present claims 131 and 136, Walling et al. teach various excipients and "auxiliary agents" (i.e. pharmaceutically acceptable excipient; please refer to Examples 1-3 and 6-8).

For present claim 132, Walling et al. teach pristine (i.e. adjuvant; please refer to column 7, lines 24-31).

However, Walling et al. does not teach pseudomonas exotoxin as a carrier.

For present claims 125, 128, 131-138, and 142, Green et al. teach vaccines comprising hapten-carrier conjugates wherein the vaccine can be multivalent (i.e. more than one hapten), the carrier is pseudomonas exotoxin, administration via intradermal, intramuscular, intraperitoneal, intraveneous, subcutaneous, oral, or intranasal routes, and adjuvants including aluminum hydroxide and aluminum phosphate can be utilized (please refer to the entire specification particularly the abstract; columns 2, 10-12; claim 9).

The claims would have been obvious because the substitution of one known element (i.e. adjuvants and carriers taught by Walling et al.) for another (i.e. pseudomonas exotoxin carrier and alum adjuvants taught by Green et al.) would have yielded predictable results (i.e. enhanced immune response compared to hapten alone) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 125-126, 128, 131-138, and 142 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,876,727 alone or in combination with Green et al. U.S. Patent 5,601,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions as claimed in U.S. Patent No. 5,876,727 claim nicotine or nicotine-derived haptens conjugated to a carrier and pharmaceutical compositions of the hapten-carrier.

For present claims 125 and 142, U.S. Patent No. 5,876,727 claims a nicotine hapten-carrier conjugate comprising the structure shown in Figures 17b and 18 (e.g. nicotine derivative hapten wherein chemical moieties may be at positions A-F and not simply utilized as a linker between the hapten and the carrier) and side chains (e.g. branch) of CJ 0, 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, and 11 (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claim 1). In addition, U.S. Patent 5,876,727 claims carriers including peptides, proteins, cholera toxin, diptheria toxin, tetanus toxoid, and pertussis toxin (i.e. bacterial toxins; please refer to claim 1). Column 13, lines 45-49 of U.S. Patent 5,876,727 teaches pseudomonas exotoxin carriers. In addition, Green et al. teaches that pseudomonas exotoxin can be utilized as a carrier for hapten vaccines (see the entire specification particularly the abstract; columns 2, 10-12; claim 9).

For present claim 126, U.S. Patent 5,876,727 claims n is from 3 to 20 (please refer to claim 1).

For present claim 128, U.S. Patent 5,876,727 claims at least two haptens coupled to the carrier (e.g. greater than one hapten; please refer to claim 2).

For present claims 131-132, U.S. Patent 5,876,727 claims a pharmaceutically acceptable carrier, an aqueous solution at a physiologically acceptable pH, and adjuvants (e.g. pharmaceutically acceptable excipient; please refer to claims 8-11).

For present claim 133-135, U.S. Patent 5,876,727 claims alum (i.e. aluminum hydroxide), MF59, or RIBI adjuvants (please refer to claims 9-10).

For present claims 136 and 139, U.S. Patent 5,876,727 claims pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 8-11).

For present claim 137, U.S. Patent 5,876,727 claims parenternal administration to a mammal (e.g. human; please refer to claims 12 and 17).

For present claim 138, U.S. Patent 5,876,727 claims oral administration (please refer to claims 12 and 18).

Therefore, the claims of U.S. Patent 5,876,727 render the presently claimed invention *prima facie* obvious.

19. Claims 125-126, 128, 131-138, and 142 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 88, 90, 103, 106, 108-109, and 128-135 of copending Application No. 11/472,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed inventions and the inventions claimed in U.S. Patent application 11/472,215 claim nicotine hapten-carrier conjugates and pharmaceutical compositions.

For present claims 125, 128, 131, and 142, U.S. application 11/472,215 claim a nicotine hapten or nicotine derivative hapten-carrier conjugate comprising the structure shown in Fig. 17b (e.g. nicotine derivative hapten) and branches of CJ 0, 1, 1.1, 1.2, 1.3, 2, 2.1, 2.2, 2.3, 3, 3.1, 4, 4.1, 5, 5.1, 6, 7, 7.1, 8, 8.1, 9, 10, and 11 wherein Y (e.g. for the CJ structures) is S, O, or NH (where the CJ structures are claimed, n = an integer, and Q is a carrier) and a T-cell epitope carrier (please refer to claims 88 and 91). In addition, U.S. application 11/472,215 defines bacterial toxin carriers as including pseudomonas exotoxin (see the specification).

For present claim 126, U.S. application 11/472,215 claim n is from 3 to 20 (please refer to claim 90).

For present claims 132, U.S. application 11/472,215 claim adjuvants (please refer to claim 103).

For present claim 133, U.S. application 11/472,215 claim alum, MF59, or RIBI adjuvants (please refer to claims 106 and 108).

For present claim 134-135, U.S. application 11/472,215 claim aluminum hydroxide or aluminum phosphate (please refer to claim 108).

For present claim 136, U.S. application 11/472,215 claim pharmaceutically acceptable carriers, adjuvants, alum, MF59, RIBI, and aqueous solutions (e.g. auxiliary agent or supplementary active compound; please refer to claims 103, 106, and 108).

For present claim 137, U.S. application 11/472,215 claim parenteral administration to a mammal (e.g. human; please refer to claims 109 and 128-135).

For present claim 138, U.S. application 11/472,215 claim oral administration (please refer to claims 109 and 128-135).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

20. Claims 125-126, 128, 131-138, and 142 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 119-135 of copending Application No. 11/472,220; claims 88-89, 95, 98-99, 102-103, 106, 108, 110, 115-116, 119-120, 123-124, and 127-128 of 11/472,219; and claims 88, 92, 97, 100, 103, 105, 110, 113, 115, 118, and 122-127 of 11/472,217. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention is drawn to a pharmaceutical composition which implies a method of treating/method of eliciting an immune response as claimed in U.S. applications 11/472,217; 11/472,219; and 11/472,220.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639

April 2, 2009